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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/461,308 | 12/15/99 | AKIMOTO T | Q56519 |

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| **ART UNIT** | **PAPER NUMBER** |
| 1655 | 9 |

**DATE MAILED:** 10/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/461,308 | AKIMOTO, TAIZO | |
| | Examiner | Art Unit | |
| | Frank W Lu | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1)☒ Responsive to communication(s) filed on *9/14/2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *13-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 25-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☒ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election without traverse of Group I, claims 1-12 and 25-36 in Paper No. 8 is acknowledged.

### *Claim Rejections - 35 U.S.C. § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, while the specification contains subject matter which describes labeled cDNA libraries and a labeled cDNA array but the specification does not provide the description for any kind of labeled organism-originated substance and any kind of carrier on which any kind of plurality of known specific binding substances differing from one another are disposed at a plurality of predetermined position wherein said any kind of specific binding substances with any kind of labeling substance in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Note that claims 2-12 are dependent on claim 1.

Claims 1-12 are directed a test piece for analyzing an organism-originated substance labeled with a first labeling substance. Note that the specification (pages 6 and 7) adequately

describes labeled cDNA libraries and a labeled cDNA array. However, the specification does not adequately describe any kind of labeled organism-originated substance and any kind of carrier on which any kind of plurality of known specific binding substances differing from one another are disposed at a plurality of predetermined position wherein said any kind of specific binding substances with any kind of labeling substance which the claims are directed to.

In view of the limited embodiments adequately description in the specification, the subject application does not reasonably convey to one skilled in the art that applicant was in possession of the full scopes of product encompass in the claims at the time of the application was filled. Therefore, the written description requirement has not been satisfied. The applicant is urged to consider narrowing the scope of the claims to that which attention has been directed.

In support of this position, attention is directed to the decision of *Vas-Cath inc. V. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are rejected as vague and indefinite over the phrase "complementary deoxyribonucleic acid (cDNA)" because it is unclear what means "complementary deoxyribonucleic acid (cDNA)" . For example, does "complementary deoxyribonucleic acid (cDNA)" mean deoxyribonucleic acids which are complementary to deoxyribonucleic acid (cDNA) or does "complementary deoxyribonucleic acid (cDNA)" means cDNA ? This rejection can be overcome by clarifying this subject matter.

***Claim Rejections - 35 U.S.C. § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al.*, (Biotechniques 23, 274-279, August 1997) in view of Stephens *et al.*, ( J. Biol. Chem. 266, 21839-21845, 1991), further in view of Guo *et al.*, (Nucleic Acids Res. 22, 5456-5465, 1994) and Liang *et al.*, (Current Opinion in Immunology 7, 274-280, 1995).

Smith *et al.*, teach automated differential display using a fluorescently labeled universal primer. In this study, the first strand of cDNA was synthesized with a 3'-anchoring $(dT)_{12}VN$

primer ( page 275, right column, second paragraph) where N can be any deoxynucleoside and V can be any deoxynucleotide other than thymidine (page 275, left column, second paragraph). The second strand of cDNA was PCR-amplified with a 3'-anchoring $(dT)_{12}VN$ primer and a 5'-FAM or 5'-HEX- or a 5'-ROX or a TRMRA-labeled universal primer (page 277, second paragraph), d[F]CTCACGGATCCGTCGA-TTTT (page 537, right column, last paragraph). This prior meets some limitations/embodiments of claims 1-8.

Smith *et al.*, do not disclose the immunization of cDNA onto a solid support, labeling cDNA with a radioactive isotope and hybridization assay.

Stephens *et al.*, teach the immunization of cDNAs onto a solid support (see page 21843, Figure 5). This prior meets some limitations/embodiments of claims 1 and 3.

Stephens *et al.*, do not disclose differential display assay, labeling cDNA with a radioactive isotope and hybridization assay.

Guo et al., teach a hybridization assay using a PCR product labeled radioactive isotope (page 5458, left column, second and third paragraphs) and producing a PCR product in the presence of a fluorescence-labeled primer (page 5457, right column, second paragraph). This prior meets some limitations/embodiments of claims 1-12.

Guo et al., do not disclose differential display assay, the immunization of cDNA onto a solid support, and hybridization assay.

Liang *et al.*, review differential display. They suggested that amplified cDNAs on gel could be detected by isotoping labeling, ethidium bromide staining and fluorescent labeling (page 277, left column, fourth paragraph).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have immobilized cDNAs labeled with a fluorescence or a radioactive isotope as suggested by Smith *et al.*, and Liang *et al.*, onto a support as suggested by Stephens *et al.*, and performed a hybridization assay as suggested by Guo *et al.*. The prior arts provided by Smith *et al.*, Lay *et al.*, and Liang *et al.*, would have motivated one having ordinary skill in the art to immobilize cDNAs labeled with a fluorescence or a radioactive isotope onto a support. The method provided by Guo *et al.*, would have motivated one having ordinary skill in the art to perform a hybridization assay using a probe labeled with a fluorescence or a radioactive isotope. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because all of these prior arts are known and are easy to use.

8. Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern *et al.*, (US Patent 5,631,734, filed on February 10, 1994).

Stern *et al.*, teach method and apparatus for detection of fluorescently labeled materials. Figure 1a schematically illustrated a device used to detect fluorescently labeled targets on a substrate. Substrate 230 comprises a number of presynthesized probes on its surface 231. The substrate on which the sequences were formed might be composed from a wide range of material, either biological, nonbiological, organic, inorganic, or a combination of any of these, existing as particles, strands, precipitates, gels, sheets, tubing, spheres, containers, capillaries, pads, slices, films, plates, slides, etc. The substrate might have any convenient shape, such as a disc, square, sphere, circle, etc. The substrate was preferably flat but may take on a variety of alternative

surface configurations. For example, the substrate might contain raised or depressed regions on which a sample was located. The substrate and its surface preferably formed a rigid support on which the sample could be formed. The substrate and its surface were also chosen to provide appropriate light-absorbing characteristics (column 3, last paragraph). A light source 100 generated a beam of light to excite the fluorescein labeled targets in the flow cell. The light source might be a argon laser that generated a beam having a wavelength of about 488 nm, which in some embodiments might be a model 2017 or model 161C manufactured by Spectra-Physics (column 5, fourth paragraph). In response to the excitation light, fluorescein labeled targets in the flow cell fluoresce light had a wavelength greater than about 520 nm. The fluorescence would be collected by the microscope objective 140 and passed to optical lens 130. In practice, light collected by microscope objective contained both fluorescence emitted by the fluorescein and 488 nm laser light reflected from the surface 231 (column 6, fifth paragraph). Figure 1c illustrated an alternative embodiment of the fluorescence detection device which is similar to the embodiment shown in Figure 1a. Two color detection were required when two different types of targets, each labeled with a different dye, were exposed to a substrate synthesized with probes. In some embodiments, fluorescein and rhodamine dyes might be used to label two different types of targets respectively. Typically, each dye would have a fluorescence peak at different wavelengths (column 8, fourth paragraph). According to the embodiment in Figure 1c, two fluorescence colors could be detected by employing a second dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter. The embodiment illustrated in Figure 1c might be

expanded by one skilled in the art to detect more than two fluorescence colors by employing an additional dichroic mirror, photomultiplier tube and associated lens, confocal pinhole and filter for each additional fluorescence color to be detected (column 9, second paragraph). Note although the detection apparatus had been illustrated primarily herein with regard to the detection of marked targets, it would readily find application in other areas. For example, the detection apparatus disclosed herein could be used in the fields of catalysis, DNA or protein gel scanning, and the like (column 16, last paragraph). This prior meets some limitations/embodiments of claims 25-32.

Stern *et al.*, do not disclose the detection of the interaction between fluorescence-labeled different cDNAs disposed at a plurality of predetermined positions on an array and fluorescence-labeled probe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the quantitative apparatus provided by Stern *et al.*, to detect the interaction between fluorescence-labeled different cDNAs disposed at a plurality of predetermined positions on an array and fluorescence-labeled probe. The method provided by Stern *et al.*, would have motivated one having ordinary skill in the art to use this quantitative apparatus to detect the interaction between fluorescence-labeled different cDNAs disposed at a plurality of predetermined positions on an array and fluorescence-labeled probe because this method is known in the art and are easy to use. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to practice this method using the quantitative apparatus provided by Stern *et al.*.

9. Claims 25 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pastore *et al.*, (Mol. Cell. Probes 10, 129-137, 1996).

Pastore *et al.*, teach the discrimination between Duchenne and Becker muscular dystrophy deletion carriers and normal females using a quantitative polymerase chain reaction (PCR) assay. Note that quantitative PCR analysis was finished by using phosphorimager-based scanning of radioactive-labeled PCR products (page 129, abstract). This prior meets some limitations/embodiments of claims 25 and 33-36.

Pastore *et al.*, do not disclose the detection of the interaction between radioactive-labeled different cDNAs disposed at a plurality of predetermined positions on an array and a hybridization probe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used phosphorimager-based scanning suggested by Pastore *et al.*, to detect the interaction between radioactive-labeled different cDNAs disposed at a plurality of predetermined positions on an array and a hybridization probe. The method provided by Pastore *et al.*, would have motivated one having ordinary skill in the art to use phosphorimager to detect the interaction between radioactive-labeled different cDNAs disposed at a plurality of predetermined positions on an array and a hybridization probe because this method is known in the art and are easy to use. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to practice this method using the phosphorimager suggested by Pastore *et al.*.

***Conclusion***

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
September 29, 2000

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
10/11/00